MOTION FILED

JUN 2 9 2007

(3)

No. 06-1582

IN THE

Supreme Court of the United States

PFIZER, INC.,
Petitioner,

v.

APOTEX, INC.
(formerly known as TORPHARM, INC.),
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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Date: June 29, 2007

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

MOTION OF WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioner. Counsel for Petitioner has consented to the filing of this brief. Counsel for Respondent declined to provide consent, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared before this Court and other federal courts in numerous cases raising important issues regarding the scope and validity of pharmaceutical patents. *See, e.g., Ferring B.V. v. Barr Laboratories*, 437 F.3d 1181 (Fed. Cir.) (patent invalidated based on inequitable conduct), *cert. denied*, 127 S. Ct. 515 (2006); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005) (patent invalidated based on inherent anticipation), *cert. denied*, 126 S. Ct. 2887 (2006); *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.* 359 F.3d 1361 (Fed. Cir. 2004) (scope of patent protection); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.) (scope of causes of action under 35 U.S.C. § 271(e)(2)), *cert. denied*, 540 U.S. 1048 (2003); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (Hatch-Waxman Act procedures for resolving drug patent disputes), *cert. denied*, 537 U.S. 941 (2002).

WLF fully supports Petitioner's request that the Court grant review in this case. WLF writes separately in order to emphasize its particular concern over the practical impact of the Federal Circuit's decision. The issue of patent obviousness

is one of significant concern to the business community. In recognition of that concern, this Court very recently granted review in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), and provided helpful guidance regarding when an invention should be deemed obvious and thus unpatentable. Rather that taking that guidance to heart, the Federal Circuit denied panel rehearing and rehearing *en banc* in this case – thereby keeping in place a pre-*KSR* decision that is at considerable tension with *KSR*. WLF is concerned that the Federal Circuit itself may draw the same erroneous conclusion from the denial of rehearing in this case as does Respondent: that the initial panel decision must be consistent with *KSR* because the panel was aware of *KSR* for a full month prior to acting on the rehearing petition yet chose not to reconsider its views. To the contrary, there is *no* evidence to suggest that the panel gave any serious consideration to the effects of *KSR* on this case. Had any such consideration been given, it is difficult to believe that the panel could have overlooked the numerous inconsistencies between its opinion and *KSR*. WLF is concerned that unless this Court, at a minimum, remands the case and compels the Federal Circuit to take another careful look at it, the Federal Circuit will accept the panel decision as an accurate translation of *KSR*'s guidance regarding when a patent should be deemed obvious.

WLF is also concerned that by issuing a decision that throws into question the validity of a wide range of pharmaceutical patents, the Federal Circuit will undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights, and thus reduce incentives for companies to invest in new, life-saving therapies.

WLF is filing this brief because of its interest in promoting the welfare of the health care industry and the public at large; it has no direct interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct

economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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QUESTIONS PRESENTED

Whether the Federal Circuit's failure to reconsider its judgment under the obviousness standard established by *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), merits granting the petition and vacating the judgment, given the tension between the *KSR* standard and the one adopted herein by the Federal Circuit, particularly in the unpredictable pharmaceutical arts?

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

STATEMENT OF THE CASE

This Court should grant *certiorari* because there are significant issues of public policy at stake. In the decision below, the Federal Circuit ignored evidence of unexpected results in an unpredictable technology, discounted the value of the invention in violation of 35 U.S.C § 101, and impermissibly focused on the manner in which the invention was made in violation of the clear language of 35 U.S.C. § 103(a). By so doing, the Federal Circuit's opinion will lead to decreased investment in research and development and increased litigation costs in the pharmaceutical industry.

In addition, the Federal Circuit's opinion contradicts this Court's recent decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), which issued while Pfizer's petition for rehearing *en banc* was pending. In *KSR*, the Court expressly stated that factors such as the predictability of the art and unexpected results are important considerations in determining whether an invention is obvious, particularly in a complex technological art, such as pharmaceuticals. Rather than taking the opportunity to conform to the standard of *KSR*,

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

the Federal Circuit denied Pfizer's *en banc* petition (over three dissenting opinions), causing continued uncertainty, especially in the area of pharmaceutical inventions. App. 39a-51a.

As stated by Judge Newman, dissenting from the Federal Circuit's decision not to rehear the case *en banc*, "[t]he panel decision changes the criteria as well as the analysis of patentability, with results of particular significance for their efforts on the conduct of R&D, the costs of drug development, and the balance between generic access to established products and the incentive to development of new products." App. 42a (Newman, J., dissenting). Similarly, Judge Lourie wrote that the Federal Circuit's "failure to recognize all such properties that may be relevant to the value of . . . a compound may doom the compound to being poured down the drain rather than becoming an important therapeutic." App. 49a (Lourie, J., dissenting). And Judge Rader explained that the "decision calls into question countless pharmaceutical patents, which in turn could have a profoundly negative effect on investments into the design and development of new life-saving pharmaceuticals." App. 51a (Rader, J., dissenting).

Accordingly, *amicus* WLF submits that this case would be a perfect vehicle to address the Court's holding in *KSR* and apply it in the context of the pharmaceuticals art. However, given the procedural posture of the case and the relevant expiration date of the patent at issue (as noted in Petitioner's brief), and the extraordinary importance of the decision to the pharmaceutical industry, *amicus* WLF requests that at the very least, this Court vacate the decision below and either remand for further proceedings in light of *KSR* or vacate the decision as moot in light of *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), for the reasons set forth in Petitioner's Brief, at 16-19.

REASONS FOR GRANTING THE PETITION

I. *Review Is Warranted Because the Federal Circuit* Improperly Discounted Evidence of Unexpected Results in an Unpredictable Technology

KSR reaffirmed that when determining whether a patent claiming a combination of prior art elements was obvious "a court must ask whether the improvement is more than the *predictable use* of prior art elements according to their established functions." *KSR*, 127 S. Ct. at 1740 (emphasis added). The Court further confirmed the value of unexpected results in assessing the nonobviousness of an invention. Citing its prior opinion in *United States v. Adams*, 383 U.S. 39 (1966), the Court explained that "[w]hen Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that *the elements worked together in an unexpected and fruitful manner* supported the conclusion that Adams's design was not obvious to those skilled in the art." *KSR*, 127 S. Ct. at 1740 (emphasis added).

The invention claimed in this case involves a distinct chemical compound – amlodipine besylate – which comprises two sub-elements chemically bound to each other: an active pharmaceutical component (amlodipine as a cation) and an acid addition salt anion (besylate a/k/a benzenesulfonate).[2] Unlike other salts in its class and those identified in the prior

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[2] In that sense, the subject matter of this patent is quite unlike the patent at issue in *KSR*, which involved a combination of pre-existing devices (a brake pedal and a sensor) tacked together in a new way. Amlodipine besylate is a distinct chemical compound, not a combination of things tacked together; it should not be viewed as a "combination" patent.

art, the besylate salt unexpectedly provided superior stability, solubility, and stickiness properties without the associated tradeoffs in bioavailability and efficacy. App. 5a-8a. The uncontested testimony and evidence show that these improvements were not predictable:

- "The district court . . . stated that the besylate salt of amlodipine was unexpectedly superior to the amlodipine salts of the prior art. . . . [I]t . . . 'clearly and unexpectedly illustrates a superior combination of properties' . . . ." App. 10-11a (citation omitted).

- "The district concluded that [a prior art article] does not direct the skilled artisan to create the besylate salt of amlodipine because [the article] discloses that besylate sulphonate was used only at a frequency of 0.25%, or 1 out every 400 drugs, prior to 1974." App. 10a.

- "Nor was there any evidence contradicting Pfizer's position that 'the superior properties at issue were not some abstract concept of "good" properties, but specific properties which solved both the sticking and instability problems of the prior art, while providing non-hygroscopicity and good solubility.'" App. 42a (Newman, J., dissenting) (citation omitted).

- "Trade-offs in salt properties are the rule, and one of skill must usually accept some undesirable properties to achieve other desirable ones. Amlodipine besylate [the claimed invention], unlike any other amlodipine salt, presented no trade-offs." *Id.*

- "[T]he besylate salt clearly and unexpectedly exhibited a superior combination of properties when compared to

what was suggested in the preferred preparation." App. 47a (Lourie, J., dissenting)(citation omitted).

- "As the testimony indicated, the properties of new pharmaceutical salt forms are entirely unpredictable." App. 50a (Rader, J., dissenting).

There was simply no basis for the Federal Circuit to ignore these unexpected results in such an unpredictable technology — particularly where there was no showing that any of the factual findings made by the district court were clearly erroneous. The Federal Circuit's decision to do so contradicts the Court's precedent in *KSR*, represents a profoundly bad public policy, and warrants review by the Court.

II. Review Is Warranted Because the Federal Circuit Completely Discounted the Value of the Invention in Violation of 35 U.S.C. § 101

The Federal Circuit avoided a review of the unexpected results by focusing only on the overall efficacy of the compound, holding "that the optimization of the acid addition salt for an active pharmaceutical ingredient would have been obvious where as here the acid addition salt formulation has no effect on the *therapeutic effectiveness* of the active ingredient . . ." App. 31a (emphasis added). As stated by Judge Rader (writing in dissent), "[t]he panel also mistakenly determined that the superior properties of the besylate did not overcome a prima facie case of obviousness because they showed no superior therapeutic value . . . ." App. 51a (Rader, J., dissenting).

With this opinion, the Federal Circuit has effectively deemed a critical field of pharmaceutical research unworthy of

patent protection. The evidence unambiguously established that the purpose of formulating amlodipine into a besylate salt was to solve problems unique to pharmaceutical development — to find a salt form that has superior stability, solubility, and "stickiness" *without* tradeoffs in bioavailability and efficacy. App. 5a-8a.

In drug development, such problems are far from trivial, and an acceptable solution is rarely predictable. The successful balancing of desirable product attributes such as drug shelf life, solubility, potency, toxicity, and efficacy is often critical to the ultimate success of a candidate drug, and medicinal chemists and formulation scientists commonly spend inordinate amounts of time, money, and effort on finding solutions to such problems.

The Federal Circuit's decision to ignore such important properties frustrates the goal of pharmaceutical research and does not represent a correct view of the law. "Therapeutic value, however, is just one property of a pharmaceutical. Other properties, such as solubility, stability, hygroscopicity, and processability, must also play a role in the analysis of advantages." App. 51a (Rader, J., dissenting). Indeed, Congress specifically authorized issuance of patents on any new and useful improvement of an existing inventions. 35 U.S.C. § 101 (2000). All that is required for patentability is a beneficial effect on some property or attribute of the basic invention that is not predictable.

This case involves a very narrowly claimed invention — a particular salt form of a single, known molecular species. The undisputed evidence in this case shows that the particular salt form claimed represents a non-obvious improvement because, in the as-yet unpredictable art of pharmaceutical formulations, the advantages of the patented invention

compared to the closest prior art salt forms could not have been reasonably predicted. If the benefits of the claimed invention at issue in the present case were indeed trivial, a competitor would have used one of the salts specifically disclosed in the prior art. As Judge Rich observed nearly half a century ago: "A monopoly on something nobody wants is pretty much . . . a nullity. That is one of the beauties of the patent system. The reward is measured automatically by the popularity of the contribution." Giles S. Rich, *Principles of Patentability*, 28 Geo. Wash. L. Rev., 393, 402 (1960).

The popularity of the present invention, and thus its value, has been endorsed in this case by the conduct of the accused infringer. In order to sell amlodipine, it was not necessary to copy the present improvement invention. Congress authorized two pathways for obtaining approval for follow-on drug products under sections 505(b)(2) and 505(j), respectively, of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355(b)(2), 355(j) (2000). Section 505(b)(2) provides a mechanism for seeking approval to market a modified but nonetheless bioequivalent formulation, such as a different and unpatented salt form. *See Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004). The infringer here, however, selected the 505(j) pathway for approval by making a literal copy of the patented salt form. Thus, the actual copying of the patented invention — in lieu of practicing any of a host of readily available, but unpatented, alternatives — demonstrates the error in the Federal Circuit's discounting of the importance of the invention.

As recognized by Judge Lourie (writing in dissent), "the panel improperly placed greater importance on the therapeutic value of a claimed compound over the value of its physical properties . . . . I read that conclusion as improperly requiring a compound to posses a specific type of improvement over the

prior art – in this case, improved therapeutic properties – to be patentable, negating other important properties, a conclusion that is not compelled by our case law and not sound." App. 47a-48a (Lourie, J., dissenting). Judge Lourie is correct and review by this Court is warranted to correct this clear error of law.

III. Review Is Warranted Because the Federal Circuit Erred in Ignoring the Express Provisions of 35 U.S.C. § 103(a)

Certiorari review is further warranted because the Federal Circuit erred in ignoring the express provisions of 35 U.S.C. § 103(a). If the decision is allowed to stand, it will adversely impact the direction and amount of pharmaceutical research.

The Federal Circuit looked at the process by which the unique properties of the besylate salt were discovered and concluded that because it was the result of "routine experimentation" it should not be patentable. App. 31a-32a; App. 48a (Lourie, J., dissenting). This, of course, is contrary to 35 U.S.C. § 103(a), which expressly states that "[p]atentability shall not be negatived by the manner in which the invention was made." App. 48a (Lourie, J., dissenting); App. 51a (Rader, J., dissenting). This provision was added to the Patent Act of 1952 to make clear that "it is immaterial whether it resulted from long toil and experimentation or from a flash of genius." P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc'y 161, 184 (1993). By emphasizing the manner in which the invention was made, the Federal Circuit failed to follow the legislative intent and important public policy goals underlying the Patent Act.

A critical element of pharmaceutical research and development involves systematic and persistent investigation using well-characterized techniques and principles. This research "is fundamental to scientific advance, and particularly for biological and medicinal products, where small change can produce large differences." App. 42a (Newman, J., dissenting). The Federal Circuit's decision is contrary to the legislative intent of § 103(a) and threatens the incentive to invest in pharmaceutical research.

IV. Review Is Warranted Because the Federal Circuit Erred When it Examined Obviousness from the Perspective of the Inventor

In *KSR*, the Court explained that "[t]he question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art." *KSR*, 127 S. Ct. at 1742; *see also Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) ("Because patentability is assessed from the perspective of the hypothetical person of ordinary skill in the art, information regarding the subjective motivations of inventors is not material."); *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) ("Inventors, as a class, . . . possess something . . . which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness . . . by inquiring into what *patentees* . . . would have known or would likely have done, faced with the revelations of references."). Here, however, the Federal Circuit analyzed the obviousness issue by improperly focusing on the *inventor's own thought processes*: "Dr Wells' testimony reflects the fact that *he believed* that amlodipine besylate would solve the problems of amlodipine maleate." App. 36a (emphasis added); *see also* 24a, 28a, 37a. The Federal Circuit's rationale was tantamount

to *sub silentio* adoption of a "reasonable to the inventor" standard.

Not only is this standard inconsistent with controlling precedent, but such a standard would obviate a large percentage of goal-oriented pharmaceutical research. Laboratory notebooks often clearly state the objective of an experiment and the hoped-for results before an experiment is performed. Testing the predictive value of laboratory research is central to the scientific-method and is not an accurate indication of the required reasonable expectation of ultimate success. The Federal Circuit's rationale provides a powerful incentive for scientists not to articulate the results they hoped to achieve in their experiments because of the risk of invalidating any patent later sought for their invention. Furthermore, a pharmaceutical company would worry that the justification to continue or begin a project could later be used as evidence that the result was expected and therefore obvious. The Federal Circuit's decision in this regard contradicts the well-established precedent of this Court, represents poor public policy, and warrants the grant of *certiorari*.

CONCLUSION

For all the above reasons, *amicus* Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of *certiorari*. At the very least, the Court should vacate the decision of the Federal Circuit and remand for further proceedings in light of this Court's decision in *KSR*.

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